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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,286	09/30/2002	Christian A. Beck	F-380	5702

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EXAMINER

ROGERS, DAVID A

ART UNIT PAPER NUMBER

2856

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,286

Applicant(s)

BECK, CHRISTIAN A.

Examiner

David A. Rogers

Art Unit

2856

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 08.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 2856

- DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent Application Publication 2003/0085266 to Simon in view of United States Patent 6,295,506 to Heinonen *et al.* and United States Patent Application Publication 2002/0072733 to Flaherty. Simon discloses an envelope (reference item 40), as best seen in Figure 5. The envelope comprises a test strip (reference item 48) located on the back of the envelope that can indicate the presence of one or more pathogens, e.g. bacteria inside the envelope. The test strip can be examined through a hole in the wall of the envelope and shows evidence of contamination using a color change. Simon does not teach the use of a barcode on the test strip that includes an identifier associated with time data. Heinonen *et al.* discloses a test strip (reference item 5) for use in analyzing biological properties of a sample. The test strip of Heinonen *et al.* is taught has having a barcode (reference item 7) that is used to identify the manufacturing batch number. Knowing information regarding the test strip would be desirable in case random sampling of the test strips, e.g. for quality control purposes, shows that certain strips are not providing the correct results, and, therefore, the remaining strips from similar batch lots have to be returned. Simon in view of Heinonen *et al.* does not teach the use of a barcode where the time information is stored by the barcode. Flaherty teaches that it is known in barcodes to include various information including type, volume, and concentration of a drug; expiration data of the device or drug; manufacture data of the device or drug; and other information such as serial numbers, lot numbers,

Art Unit: 2856

hospital name, clinician name, and patient name. Clearly, Heinonen *et al.* in view of Flaherty teaches that barcodes can be used to store a wide variety of information pertinent to the device with the barcode. Date and time information, such as the date and time of manufacture, would be beneficial as certain test strips contain reagents whose "shelf life" is limited so that, if used after the expiration date, the test strip may not function correctly. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Simon with the teachings of Heinonen *et al.* and Flaherty in order to obtain a test strip with a barcode that stores information such as dates and times.

3. Claims 2, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon in view of Heinonen *et al.* and Flaherty as applied to claim 1 above, and further in view of United States Patent 4,840,919 to Attar and United States Patent 6,254,846 to Robinson, Jr. Simon teaches an envelope with a test strip. The test strip changes color upon contact with certain pathogens. The test strip, as shown in Figure 5, is located on the back side of the envelope. Simon does not teach a test strip mounted on a holder. Mounting the test strip on a holder would have been an obvious modification to the device of Simon. Furthermore, one would be motivated to use a holder so as to avoid contamination of the test region during handling and placement of the test strip in the envelope. To further support this, Attar shows that it is well known to produce test strips (reference item 10) comprising a base (reference item 12) that is larger than the test portion (reference item 22). This test strip changes color in the presence of specific compounds. The fact that the applicant has attached their test strip and holder to a carrier prior to insertion into an envelope is not patentably distinct over the teachings of Simon in view of Attar. The applicant's carrier may provide additional stiffness to the holder, but it does not make the device operate in a new or otherwise novel manner. Furthermore, the use of the carrier may well inhibit the functionality of the test strip as any pathogens present would no longer have direct path to the test strip. Attempts to overcome this deficiency by providing holes on the carrier would also be an obvious modification over the device of Simon in view of Attar. To further support this, Robinson, Jr. teaches that it is known to

Art Unit: 2856

provide a hole (reference item 14a) on the cover (reference item 14) to allow the air with the pathogens to reach the test portion. One of ordinary skill in the art would know that increased circulation around the test portion increases the likelihood that the pathogens would be detected by the test strip. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Simon in view of Heinonen *et al.* and Flaherty with the teachings of Attar and Robinson, Jr. to provide an envelope with a test strip wherein the test strip is located on a holder so that the integrity of the strip is not compromised during handling and placement.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon in view of Heinonen *et al.*, Flaherty, Attar, and Robinson, Jr. as applied to claims 1 and 2 above. Simon in view of Heinonen *et al.*, Flaherty, and Attar teaches an envelope with a test strip, wherein the test strip comprises a larger base member upon which is mounted the testing portion. As stated above the larger base portion allows the test strip to be handled and placed in an envelope without compromising the test region. The test strip of Simon is clearly smaller than the envelope. Simon in view of Heinonen *et al.*, Flaherty, and Attar does not teach an envelope with a test strip where the test strip moves inside the envelope. Allowing the test strip to move inside the envelope would have been obvious to one of ordinary skill in the art. It is well known and commonly practiced that smaller items are placed in larger envelopes such that the smaller items move during the mailing process. Doing the same with the test strip does not involve any inventive step. And, as Robinson, Jr. clearly states, "it is unimportant as to where the...indicator is located except that it must be in communication with the interior of the envelope and visible from an exterior of the same" (column 6, lines 49-53). Having the item test strip move would obviously require several more holes in the envelope thereby risking exposure of the contents of the envelope to outdoor environments or other contaminants such as inks from automated processing equipment, spills or leaks from other sources, or damage due to the fact that the holes catch or bind with the automated processing equipment or other items such as clasps on larger envelopes. Furthermore, if

Art Unit: 2856

the test strip was allowed to move then the envelope would not be useful for automated processing equipment such as the method disclosed by Robinson, Jr. (column 6, lines 42-49) since the test strip would have to be located and examined manually. This would obviously add to the time and expense of mail processing if large quantities of envelopes with movable test strips were handled, with time spent looking for the test strip and then reading the strip, which could then cause exposure of the pathogens to the handler. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Simon in view of Heinonen *et al.*, Flaherty, Attar, and Robinson, Jr. to provide an envelope with a test strip wherein the test strip is allowed to move in the envelope.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon in view of Heinonen *et al.* and Flaherty as applied to claim 1 above, and further in view of Robinson, Jr. Simon in view of Heinonen *et al.* and Flaherty teaches an envelope with a test strip. The test strip changes color upon contact with certain pathogens. The test strip, as shown in Figure 5, is located on the back side of the envelope. One of ordinary skill in the art would clearly recognize that the test strip can be located anywhere on the envelope, including the front, as long as it does not interfere with standard placement of items such as postage, return address, or the delivery address. However, in the event that such a relocation was not obvious, Robinson, Jr. teaches an envelope (reference item 20) with a toxin indicator (reference item 10) that is in communication with the interior of the envelope. The indicator shows the presence of contaminants such as various bacteria via a color change. Furthermore, Robinson Jr. teaches that the location of the indicator should be fixed if the envelope was to pass through an automated processing system, but that its location is unimportant in manual processing systems (column 6, lines 42-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Simon in view of Heinonen *et al.* and Flaherty with the teachings of Robinson, Jr. to provide an envelope with a test strip capable of indicating the presence of various pathogens inside the envelope wherein the test strip is located on the front of the envelope.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
 - a. United States Patent Application Publication 2002/0060247 to Krishnaswamy *et al.* discloses that it is known to use test strips with identifier codes, such as an expiration date, and that a barcode is reader is the preferred means to enter the data/.
 - b. United States Patent Application Publication 2002/0123671 to Haaland discloses that it is known to use test strips with barcodes.
 - c. United States Patent Application Publication 2003/0111357 to Black discloses that it is known to place barcodes on test strips.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

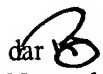
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (703) 305-4451. The examiner can normally be reached on Monday - Friday (0730 - 1600).

Art Unit: 2856

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (703) 305-4705. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

dar 
November 6, 2003


HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800